

EXHIBIT 43

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE JOHNSON & JOHNSON
TALCUM POWDER PRODUCT
MARKETING, SALES
PRACTICES AND PRODUCTS
LIABILITY LITIGATION**

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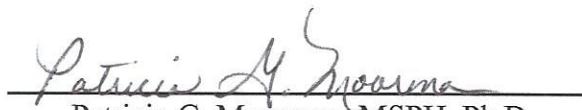
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SUPPLEMENTAL EXPERT REPORT OF

PATRICIA G. MOORMAN, MSPH, Ph.D.

Dated: November 15, 2023



Patricia G. Moorman, MSPH, Ph.D.

Supplemental Report on Talc and Ovarian Cancer
November 2023
Patricia Moorman, Ph.D.

This report serves as a supplemental report to my 2021 addendum and my 2018 report, which together describe my review of the scientific and medical evidence on genital talc use and ovarian cancer risk. Since the submission of my 2018 and 2021 reports, additional relevant literature on talc and ovarian cancer has been published including peer-reviewed papers describing epidemiologic analyses of talc use and ovarian cancer, a screening assessment of talc by Health Canada, papers related to mechanisms of talc carcinogenesis, and several reviews, editorials and letters to the editor. The attached list of references identifies materials I considered and found most relevant to this subject.

In my 2018 report, I described my methodology to review, assess, and weigh material relevant to the inquiry of whether there is an association between talcum powder product use and ovarian cancer. I used the same critical method of review with this new material, for individual publications and in relation to the cumulative body of evidence on this subject. I considered the design of the studies, possible biases and limitations and the likely impact of those limitations on the reported study outcomes. Generally, this new material provides additional evidence that supports the association between talc and ovarian cancer risk and reinforces and strengthens my opinion that genital use of talc is a cause of ovarian cancer.

1. New Peer-Reviewed Epidemiologic Analyses Related to Talc and Ovarian Cancer

Three peer-reviewed papers (Davis, et al., 2021; Phung, et al., 2022; Woolen, et al. 2022)[1-3] describe new epidemiologic analyses of talc or genital powder use and ovarian cancer risk. Each of these papers combined data from multiple studies, most of which had been included in prior publications on talc use and ovarian cancer risk, to analyze different aspects of the association, including comparisons between African American and white women,(Davis, et al., 2021)[1] comparisons of women with and without endometriosis,(Phung, et al., 2022)[2] and the risk of ovarian cancer among frequent users of talcum powder products(Woolen, et al., 2022).[3] A fourth paper (O'Brien, et al., 2023)[4] did not specifically analyze the association between talc

use and ovarian cancer risk, but instead was a methodologic paper on patterns of talc use and reliability of self-reported exposure. Below, I describe each of these papers, their most relevant findings and how they contribute to the overall body of literature on talc use and ovarian cancer risk.

Davis CP, et al. Genital powder use and risk of epithelial ovarian cancer in the Ovarian Cancer in Women of African Ancestry Consortium. Cancer Epidemiology Biomarkers Prev 2021; 30: 1660-1668.[1]

This report from the Ovarian Cancer in Women of African Ancestry Consortium combined data from five studies (four case-control studies and 1 cohort, 3,420 cases and 7,881 controls) to evaluate the association between genital powder use and ovarian cancer in African American and White women. Importantly, I am a co-author on this paper. Four of the five studies (AACES, LACOCS, NCOCS, WHI) included in the analysis had previously published results from their individual study on ovarian cancer and talc use. Odds ratios (ORs) for ovarian cancer in relation to genital powder use were calculated for each study and then combined in a meta-analysis to calculate ORs for the overall study population, for African Americans and for Whites. Analyses were also conducted by histologic type, frequency of use and duration of use.

The overall findings from the analyses were that an increased risk of ovarian cancer among ever users of talc was observed for the entire study population (pooled OR 1.32, 95% CI 1.17, 1.48), for African American women (pooled OR 1.22, 95% CI 0.97-1.53) and for white women (pooled OR 1.36, 95% CI 1.19-1.57). Differences in risk by histologic type were reported for African American women, with higher risk for high-grade serous (OR 1.31, 95% CI 1.01-1.71) than for other histotypes (OR 1.05, 95% CI 0.75-1.47), whereas similar risk by histotype was found for White Women (OR 1.33, 95% CI 1.12-1.56 for serous vs 1.38, 95% CI 1.15-1.66 for all other histotypes). No trends of higher risk with greater frequency of use (> once per week vs. \leq once per week) or longer duration of use (>20 years vs. \leq 20 years) based on broad categorizations of these variables were apparent. The available data did not allow for consideration of both frequency and duration. The authors noted that tests of heterogeneity did not indicate differences in effect estimates across study sites “highlighting that the results from our included prospective study (WHI) were not materially different from the 4 retrospective case-control studies.”

Phung, MT, et al. Effects of risk factors for ovarian cancer in women with and without endometriosis. Fertility Sterility 2022; 118: 960-969.[2]

This paper reported analyses from the Ovarian Cancer Association Consortium (OCAC) in which the investigators examined “the associations between 10 well-established ovarian cancer risk factors and risk of ovarian cancer among women with vs without endometriosis.” Data came from eight population-based, case-control studies in the United States and Australia. Some of these studies were included in previous published analyses from OCAC on talc and ovarian cancer.^[5] The analyses for talc were based on 4,851 ovarian cancer cases (of whom 461 had endometriosis) and 7,919 controls (569 with endometriosis). Increased risk of ovarian cancer with genital talc use was observed for both women with endometriosis (OR=1.38, 95% CI 1.04-1.84) and women without endometriosis (OR=1.12, 95% CI 1.01-1.25). No increased risk was observed for non-genital use of talc.

The paper’s discussion section addressed the higher risk of ovarian cancer with genital talc use among women with endometriosis than women without endometriosis. Although not a statistically significant interaction, the higher risk among women with endometriosis is consistent with inflammation playing a role in the development of ovarian cancer. Endometriosis is considered an inflammatory disease and inflammation has been proposed as a biologically plausible mechanism for talc’s association with ovarian cancer. Therefore, the higher risk among women with both endometriosis and genital talc exposure is consistent with a role for inflammation in the development of ovarian cancer.

Woolen SA, et al., Association between the frequent use of perineal talcum powder products and ovarian cancer: a systematic review and meta-analysis. J Gen Intern Med 2022; 371: 2526-32.[3]

This report described a systematic review and meta-analysis focused on studies that had data on frequent use of perineal talcum powder. Because previously published meta-analyses of genital talc use and ovarian cancer focused primarily on ever vs. never use of talc, the authors desired to examine the risk among women who reported higher use of genital talc to provide a more meaningful assessment of the risk of ovarian cancer. Frequent use was based on reports of number of applications per week (at least 4 times per week), per month (at least 20 times per month) or total lifetime applications (>10,000). Using these criteria, they analyzed data from 10

published case-control studies and one cohort study (the Nurses Health Study-I (NHS)). The NHS had not published results on the highest frequency of talc exposure, however the NHS investigators provided these data to the study authors for inclusion in the meta-analysis. The analyses were based on 5,692 ovarian cancer cases and 8,143 controls from the case-control studies and 850 cases in the cohort of 52,191 women from the NHS.

The summary OR combining data from all 11 studies was 1.47 (95% CI 1.31-1.65). The reported OR for the NHS cohort study (1.40, 95% CI 1.17-1.68) was not markedly different than the overall OR for case-control studies (1.49, 95% CI 1.29-1.72). A series of sensitivity analyses were performed in which studies were excluded for various reasons (e.g., lower study quality scores, studies that combined perineal and other talc use). Findings from the analyses in which one or more studies were excluded were substantively similar to the overall findings in terms of the magnitude of the summary OR, the homogeneity of the studies and the lack of evidence of publication bias.

As the authors noted in the discussion, the pooled OR of 1.47 was higher than the summary ORs from other published meta-analyses or pooled analyses, which ranged from approximately 1.25 to 1.35.[6-11] This is to be expected given that other meta-analyses defined the exposure as any use of talc whereas the exposure was defined as frequent use of talc in this meta-analysis. The higher reported pooled OR for frequent talc use in this meta-analysis as compared to the OR reported in meta-analyses reporting on ever use of talc is supportive of a dose-response relationship between genital talc use and ovarian cancer.

O'Brien KM, et al., Douching and genital talc: patterns of use and reliability of self-reported exposure. Epidemiology 2023; 34: 376-384.[4]

This report, which uses data from the Sisters Study cohort, is a methodologic paper that examines patterns of use of talc or douching across the lifespan and compares the reliability of responses from surveys administered at two different time points. To put this in context, the association between talc use and ovarian cancer in this cohort was reported in a 2016 paper by Gonzalez, et al.[12] The main finding was that talc users had a relative risk for ovarian cancer of 0.73, 95% CI 0.44-1.20). This finding is an outlier when considering the overall body of literature as it is only 1 of 3 studies out of the 27 studies included in the major meta-analyses[9-11] that

reported a relative risk less than one. As described in my 2018 report, the exposure measure used in the analyses by Gonzalez, et al. was sub-optimal in that it was based only on talc use in the 12 months prior to enrollment, which resulted in a prevalence of talc use in the cohort of 14%. This prevalence of talc use was far below what has been reported in most other case-control and cohort studies (typically around 40%)(e.g., [13-17] which suggests there had been considerable misclassification of the exposure and raises serious concerns about the findings reported by Gonzalez, et al. The data presented in O'Brien's report help to quantify the extent of misclassification of talc exposure.

O'Brien, et al. compared reported use of talc in the Sisters Study cohort based on responses given in the baseline enrollment questionnaire (2003-09) and those given on a more detailed questionnaire on a follow-up survey (2017-2019). The baseline survey had asked about talc use in the 12 months prior to enrollment in the cohort and at age 10-13. The later survey queried about talc use during each decade of life from teens up through the 70s, age at first and last use, use in relation to menopause and frequent use defined as >1 time per month.

Some of the key findings as reported by the authors were that there was generally good consistency in reported talc use between the two surveys, which could have ranged between 8 and 16 years apart in time depending on when the women completed the surveys. The prevalence of talc use in the cohort based on the more detailed reporting in the later survey was 32%, which was higher than the 27% reporting talc use in the original survey. The higher prevalence in the later survey was to be expected because the original survey asked about talc use only at two timepoints (age 10-13 and at cohort baseline) and would have missed any women who initiated use after age 13 or discontinued use more than a year before enrolling in the cohort. However, a critical observation is that the Gonzalez report[12] on talc use and ovarian cancer risk categorized women as exposed to talc based only on one timepoint (cohort baseline). Their reported prevalence of talc use was only 14%, as compared to the 32% prevalence described in this paper based on more complete ascertainment. Therefore, the prevalence of talc use in the cohort was more than two times higher than the prevalence of talc use on which the Gonzalez analysis was based. Given this profound level of misclassification of the main exposure variable

of talc, it casts serious doubts on the findings reported for talc and ovarian cancer by Gonzalez, et al. in 2016.

O'Brien et al. also reported on the agreement between reported use of talc in the 12 months prior to enrollment on the two surveys, overall and by various characteristics including cancer status (Supplemental Materials - eTable 6 – <http://links.lww.com/EDE/C6>). They reported that use of talc at that time point was more commonly reported on the baseline enrollment survey (27%) than on the follow-up survey (21%) overall. However, among women who had had an intervening ovarian cancer diagnosis, the reported prevalence was higher on follow-up survey (33%) than at baseline (28%). The authors stated that this could be an indication of recall bias. However, they qualified it by noting that the numbers may not represent all ovarian cancer cases as approximately half of the women diagnosed with ovarian cancer had died before the follow-up survey. They also noted that “12 months before enrollment age made for a vague benchmark”.

These findings deserve comment for several reasons. First, the percentages presented in (eTable 6) for prevalence of use in the 12 months prior to enrollment are inconsistent with numbers presented in other parts of the paper. At the top of Table 3, the authors reported that 14% of the cohort reported talc use in the 12 months prior to enrollment, which is half the prevalence cited above (27%) from eTable 6. In light of this apparent error, it's unclear how any conclusion can be drawn about recall bias from these data.

Second, if the data are correct (which does not appear to be the case), the number of ovarian cases is fairly small (n=125). Therefore, the difference in reported prevalence at the two timepoints (28% vs. 33%) would have been only 6 more women reporting talc use at a timepoint. Again, the authors describe 12 months before enrollment as a vague benchmark, so some difference in reporting would be expected.

Third, the interpretation of possible recall bias should be put in the context of the characteristics of the cohort and the timeframe of the follow-up survey. The Sisters Study comprises women who are at increased risk for ovarian cancer and breast cancer by virtue of having a sister with a history of breast cancer. In addition, the cohort was highly educated with over 80% having greater than high school education. The follow-up survey was conducted in 2017-2019, a time when there many TV ads and other mentions of talc and ovarian cancer in the

press. As I described in my 2018 report, recall bias is more likely in situations where the study participants are aware of the study hypothesis and when there has been considerable media attention on the exposure/disease outcome. Given that the cohort was a group of highly educated, high-risk women, it is likely that they were more aware of known and suspected risk factors for ovarian cancer than women from the general population. Their awareness of talc as a risk factor for ovarian cancer would have been heightened by the media attention during the timeframe when they completed the survey. Therefore, although the evidence O'Brien et al. presented for possible recall bias is suspect because of the inconsistency in data presented in the paper, it also has to be interpreted in the context that the degree of recall bias in this study, due to the high-risk, highly educated cohort and the timeframe of the survey, is likely to be greater than in the studies of average-risk women conducted before there was widespread media attention on talc and ovarian cancer. It would not be reasonable to extrapolate from these data and conclude that there was substantial recall bias in the population-based studies conducted many years earlier.

Conclusions from New Epidemiologic Analyses of Talc and Ovarian Cancer

The analyses from the four papers described above all used data from studies that had been included in previous publications reporting on talc use and ovarian cancer risk. Some of the key new findings reported include: 1) Similar overall findings for African American and white women of increased risk of ovarian cancer among genital powder users, with a suggestion of possible racial differences in the association by histotype;[1] 2) Women with endometriosis who use talc appear to be at higher risk for ovarian cancer than women without endometriosis who use talc, a finding that is consistent with inflammation being a possible mechanism for the development of ovarian cancer.[2] 3) Women who were frequent users of talc had higher risk of ovarian cancer than what had been reported in prior meta-analyses comparing ever talc users to never users, which is consistent with a dose-response relationship. Similar findings were observed for the case-control studies and the one cohort study included in the analysis;[3] 4) The key findings reported in the methodologic paper from the Sisters Study [4] include: a) The prevalence of talc use in the cohort based on a more recent survey was 2.3 times higher than the prevalence used in the 2016 report on talc and ovarian cancer in this cohort by Gonzalez, et al.[12] In other

words, over half of the talc users in the cohort had been misclassified in the Gonzalez study. b) The authors report that there may be evidence of recall bias in regard to talc use among women with ovarian cancer, however because of inconsistencies in the data presented, and the characteristics of the cohort and timing of the survey, this conclusion may be incorrect and certainly not generalizable to other study populations.

Overall, the new data, with refinements in the types of analyses performed, strengthen my opinion that genital talc use is a cause of ovarian cancer.

2. Health Canada – Screening Assessment of Talc (Chemical Abstracts Registry Number 14807-96-6, April 2021[18]

This report from Health Canada (the Canadian counterpart of the U.S. Food and Drug Administration) describes a screening assessment of talc conducted by the Minister of Health and Minister of the Environment within the government of Canada with the stated purpose of determining whether talc presents a risk to the environment or to human health. In evaluation of the health risks, they considered data from 34 epidemiologic studies (30 case-control and 4 cohort studies) that were included in the three most recent meta-analyses by Berge, et al (2018), Penninkilampi, et al. (2018) and Taher, et al. (2019).[9-11] They noted that a high percentage of case-control studies in the meta-analyses (85%-92%) as well as three of the four reports from cohort studies reported ORs greater than 1, although not all were statistically significant. The review carefully considered limitations of both cohort studies (e.g., limited assessment of talc exposure, limited duration of follow-up, age of the cohorts and representativeness of the cohorts) and case-control studies (e.g. recall bias, small sample sizes, limited exposure information for some studies, low response rates). They evaluated causation applying the Bradford-Hill considerations of Strength, Consistency, Biological Gradient and Biological Plausibility and then further addressed Bias and Confounding. In regard to the biological plausibility of talc as a cause of ovarian cancer, this report did not mention asbestos as a constituent of talc products that they took into consideration when assessing biological plausibility. In other words, there are plausible biological mechanisms for the carcinogenicity of talc, regardless of whether asbestos is in talcum powder products. It is noteworthy that the investigators took into consideration not only the

published epidemiologic and mechanistic studies but also the expert reports from both plaintiff and defendant witnesses in the talc litigation.

While acknowledging some limitations in the body of evidence, the report stated that “there is a high degree of consistency in the epidemiological studies across several decades conducted in different parts of the world. Although there are uncertainties related to bias, there is confidence in the robustness of the available database for use in characterizing ovarian cancer risk attributed to talc exposure. Furthermore, the available data are indicative of a causal relationship.”

The Health Canada report presented a comprehensive and exhaustive review of the evidence on ovarian cancer risk associated with genital talc use, considering epidemiologic studies, mechanistic studies and expert reports from both defense and plaintiff witnesses in talc litigation.[18] Their overall approach was balanced, considering strengths and weaknesses of both case-control and cohort studies and the likely impact of possible biases on the reported relative risks. Their overall conclusion that there is a causal relationship between talc and ovarian cancer is concordant with the conclusion I reached in my prior reports. This report supports and strengthens my opinion that genital talc use can cause ovarian cancer.

3. Other Reviews, Editorials and Correspondence

Below I describe other recently published literature related to talc use and ovarian cancer risk, including reviews, editorials and correspondence. These articles did not report new data analyses, but rather presented their qualitative assessment of the literature or responded to such assessments.

Lynch HN, et al. Systematic review of the association between talc and female reproductive tract cancers. Frontiers in Toxicology August 2023[19]

The stated purpose of this review was to “critically evaluate the possible relationships between perineal exposure to talc-containing products and female reproductive tract cancers.” This systematic review presented data from 29 epidemiologic studies of ovarian cancer (3 cohort and 26 case-control studies) but did not combine the data in a meta-analysis to come up with a summary relative risk estimate. The authors assigned quality scores to each of the studies based on five domains (study participation, exposure assessment, outcome assessment, potential

confounding, analysis), which resulted in all of the cohort studies being assigned an overall quality score of “medium” whereas 11 of the 26 case-control studies were assigned a quality score of “medium” and the remaining 15 a quality score of “low”. Notably, all but one of case-control studies were assigned a score of “low” on exposure assessment, whereas two of the three cohort studies were rated as “medium”, despite the recognition that many of the case-control studies had more detailed information on talc use than the cohort studies. The authors then qualitatively assessed the evidence to come up with an overall conclusion: “Despite the modest number of high-quality epidemiological studies addressing genital use of talc and ovarian cancer, the better-quality studies tend to be negative, providing insufficient evidence and an inadequate basis for concluding with any confidence that there is a causal connection.”

Throughout this paper, the authors largely dismissed positive findings from case-control studies as being “overshadowed by recall and reporting bias, enhanced by the unavoidable exposure to news stories, social media and advertisements purporting that talcum powder causes cancer”. There appears to be a pattern of the authors being clearly biased in their evaluation of case-control studies as compared to cohort studies.

For example, in regard to study quality ratings, the Gates and Gonzalez cohort studies were both rated “low” on exposure assessment and “medium” on all other study domains and were given an overall score of “medium”. In contrast, three case-control studies with identical ratings (Merritt, Jordan and Wong) and four with higher ratings (Ness, Cramer 1999, Green, Cook) were given overall scores of “low”. It is unclear why case-control studies with identical or better ratings on individual quality domains would be given a lower overall study quality score than the cohort studies.

Another indication of bias against case-control studies is their statement in their conclusion: “Despite the modest number of high-quality epidemiological studies addressing genital use of talc and ovarian cancer, the better-quality studies tend to be negative, providing insufficient evidence and an inadequate basis for concluding with any confidence that there is a causal connection”. This statement is clearly inconsistent with the data presented in their paper. A total of 3 cohort studies and 11 case-control studies received an overall study quality score of “medium”, the highest score that any study was assigned. Of these 14 studies, all but the

Gonzalez study reported relative risks greater than 1, and 8 of these studies reported statistically significant increased risks. So clearly, the higher quality studies do not tend to be negative, but rather show a very consistent increased risk of ovarian cancer with talc use.

These examples (and others that could be cited) suggest that the paper's authors largely discounted findings from case-control studies, which comprise roughly 90% of the studies. In some cases, their statements contradict data presented in their paper. Because of the contradictions and apparent bias in the interpretation of study findings, Lynch, et al.'s conclusion of "suggestive evidence of no association between perineal application of talcum powders and risk of ovarian cancer" is not credible.

Wentzensen N, O'Brien K. Talc, body powder, and ovarian cancer: a summary of the epidemiologic evidence. Gynecologic Oncology 2021; 163: 199-208

Wentzensen and O'Brien's review [20] summarized the epidemiologic data on talc, body powder and ovarian cancer, focusing primarily on recent meta-analyses and pooled analyses.[5, 9-11, 21] They addressed associations between talc and ovarian cancer overall, by histologic type, by tubal ligation and hysterectomy status, and by race. The authors conclude that "the epidemiological data from case-control studies and cohort studies suggest that there may be a small, positive association between genital powder use and ovarian cancer, which may be limited to women with patent reproductive tracts". They also state that the results consistently demonstrate a positive association with serous ovarian cancers, and possibly endometrioid cancers, and that the positive association may be limited to women with patent reproductive tracts. In their consideration of biases, they make the statement that because the association from case-control studies may be exaggerated by recall bias and the association from cohort studies may be underestimated by cohort studies because of limited exposure information, the association probably lies somewhere between the estimates. The authors also considered biological mechanisms for the association between talc and ovarian cancer including inflammation and "contamination of talc products with asbestos and other carcinogenic components (e.g., quartz)", but conclude that the current causal mechanisms are unknown.

Cramer [22], in correspondence to the journal, addressed some of the comments the authors (Wentzensen and O'Brien) made about recall bias and confounding by indication,

disputed their conclusion about limited public health relevance, and pointed out recent experimental studies that speak to mechanisms of talc carcinogenesis. Finally, Cramer noted that Wentzensen and O'Brien had not referenced the report from Health Canada that concluded there was a causal association between talc use and ovarian cancer. The Health Canada report came out at approximately the same time the authors submitted their paper (April 2021) and may not have been available to the authors for review, however Cramer thought it was worthy of them responding to it.

Micha JP, et al. Talc powder and ovarian cancer: what is the evidence? Arch Gynecol Obstet 2022; 306: 931-933.[23]

This very brief opinion piece purports to evaluate the evidence on talc powder, with a very limited and misleading description of possible mechanisms of action and incomplete description of clinical evidence. In regard to clinical evidence, the authors cite only 5 case-control studies, all published before 1999, and made no mention of the much larger body of evidence from case-control studies, including more recent studies that were larger and more informative. Further, the study that the authors cite as not demonstrating a relationship between talc and ovarian cancer (Ref 4, Cramer, 1982) actually reported a substantially increased risk. The authors, in their discussion, erroneously state that “cosmetic talc has been asbestos-free for several decades”, with no mention of the FDA’s finding of asbestos in Johnson & Johnson baby powder, that led to the withdrawal of the product from the market. In short, because of numerous errors and omissions in this review, it does not present any credible evidence related to talc and ovarian cancer.

Tran and Egilman [24] responded to the Micha paper in correspondence to the journal. Their rebuttal addressed numerous points including the presence of asbestos in talc, the evidence on talc particles reaching the ovaries, the possible impact of recall bias, and biomarkers of talc powder and ovarian carcinogenesis.

Slomovitz B, et al. Asbestos and ovarian cancer: examining the historical evidence. Int J Gynecol Cancer 2021; 31: 122-128 [25]

This review was undertaken to examine the evidence that asbestos is causally related to ovarian cancer. As noted by the authors, the World Health Organization’s International Agency

for Research on Cancer (IARC) has found asbestos to have a clearly established causal association with ovarian cancer. Slomovitz, et al. also state that the presence of asbestos in baby powder is the underpinning for the lawsuits against Johnson & Johnson. The authors qualitatively reviewed evidence on which IARC reached their conclusion that asbestos causes ovarian cancer, largely studies of occupational exposure to asbestos. The major points of their paper were that there was some inconsistency in findings across studies of asbestos and ovarian cancer and that there is the possibility of misclassification of ovarian cancer outcomes in the studies due to the difficulty distinguishing ovarian cancers from peritoneal malignant mesotheliomas. They conclude that further scientific investigation is needed to clarify the causal association between asbestos and ovarian cancer.

Certain of the points made by the authors are valid. There are some inconsistencies across studies in the magnitude of the association between asbestos and ovarian cancer, however given the relatively small sizes of the occupational cohorts and relatively low incidence of ovarian cancer, some variation across studies would be expected. It is also possible that cases of peritoneal mesothelioma were misdiagnosed as ovarian cancer, but the converse is also true that some ovarian cancers were incorrectly classified as other types of cancer. Despite limitations in the available data, IARC and other agencies (e.g. U.S. Environmental Protection Agency) that have comprehensively reviewed the evidence have concluded that asbestos causes ovarian cancer [26, 27] and that there is no safe level of exposure to asbestos.

It is also important to point out that there are several mischaracterizations in the first paragraph of the introduction to the paper. The authors state that the thousands of lawsuits by women with ovarian cancer claim that their cancers were caused by asbestos. The lawsuits claim that the ovarian cancers were caused by exposure to talcum powder products. The fact that asbestos has actually been found in talc products (not just that they “may have contained asbestos” as the authors state) bolsters the biologic plausibility for talc products causing ovarian cancer however there are other plausible biologic mechanisms beyond asbestos by which talc exposure could cause ovarian cancer. Of note, the Health Canada report described above, which concluded that use of talc products causes ovarian cancer, did not specifically reference asbestos in talc.

This report attempted to cast doubt on whether asbestos is a cause of ovarian cancer. This opinion clearly conflicts with conclusions reached by IARC and EPA. No new data were presented in the paper and there was some mischaracterization of the issues related to talc use and ovarian cancer, therefore this paper did not alter my opinion about talc as a cause of ovarian cancer.

Correspondence re: O'Brien, et al. Association of powder use in the genital area with risk of ovarian cancer. JAMA 2020; 323: 49-59.

The 2021 addendum to my report described the paper by O'Brien, et al. in which they presented a pooled analyses of data from four cohort studies (Nurses Health Study, Nurses Health Study II, Sisters Study and Women's Health Initiative).[21] The overall findings of their analysis of these cohorts was that there was a statistically significant increased risk of ovarian cancer among talc users in women with patent reproductive tracts (HR 1.13, 95% CI 1.01-1.26) and an elevated, but not statistically significant HR overall (1.08, 95% CI 0.99-1.17). Several authors [28, 29] submitted letters to the editor of the journal raising concerns about the interpretation of the findings and certain limitations of the studies, and O'Brien and colleagues responded to those comments. I had not discussed these comments in my 2021 addendum.

Cramer [28] raised concerns about the incompleteness of talc exposure in each of the cohorts, due to the manner in which the cohorts ascertained use of talc. He also noted that most of the women in the cohorts were postmenopausal at the time of assessment of exposure, whereas some case-control studies indicate that the association between talc use and ovarian cancer is stronger for pre-menopausal women than post-menopausal women. Harlow, et al. [29], in a separate letter, made similar points about the likely misclassification of talc exposure in the cohorts. They also noted the median age at which talc exposure was assessed (57 years) and how restricting their analyses to women who survived to that age without having developed ovarian cancer could introduce substantial selection bias (i.e., depletion of susceptibles). They characterized O'Brien, et al.'s statement of "there is no statistically significant association based on a HR of 1.08 (95% CI 0.99-1.17)" as "poor practice in population and clinical research". Harlow, et al. concluded that the 13% increased risk of ovarian cancer in women with intact genital tracts that was observed in the analysis by O'Brien et al., despite the methodological issues that would

tend to result in bias toward the null, should be taken as evidence of an effect of talc on ovarian cancer.

O'Brien, et al. responded to the criticisms raised in both letters.[30] They acknowledged that there was likely misclassification of genital powder exposure, which may have biased their results toward the null. They also agreed that the analyses limited to women with intact reproductive tracts should not be discounted because their tests of heterogeneity between women with and without intact genital tracts were not statistically significant and further state that they "agree that the positive association among women with patent reproductive tracts (HR, 1.13; 95% CI, 1.01-1.26) is consistent with the hypothesis that there is an association between genital powder use and ovarian cancer."

This correspondence, particularly the responses from O'Brien, et al., is particularly useful in the assessment of the data on genital talc and ovarian cancer from cohort studies. While the "lack of association in cohort studies" is often cited as evidence against talc being a cause of ovarian cancer, O'Brien et al. states clearly that there was a positive association among women with patent reproductive tracts. Furthermore, these authors acknowledge that the notable limitations in most of the cohort studies, especially exposure misclassification and the age of the cohorts, are likely to result in a bias to the null. Therefore, the relative risks reported in cohort studies are likely to be underestimates of the true relative risk. Both of these acknowledgments from the authors of the pooled analysis of cohort studies clearly support that the data from cohort studies are consistent with data from case-control studies in regard to the increased risk of ovarian cancer among women who used talc products.

Conclusions from Other Reviews, Editorials and Correspondence

The reviews and correspondence described in this section did not present new data analysis, but rather an evaluation or commentary on existing literature. As described above, there was a range of quality and fairness in evaluating the literature. Overall, because these papers were not presenting new data on talc and ovarian cancer, they did not impact my overall opinion that talc is a cause of ovarian cancer.

4. Overall Conclusions

Recently published literature on the risk of ovarian cancer among women who used genital talc included additional analyses addressing different aspects of talc use and ovarian cancer risk (e.g., frequent use, use among women with endometriosis, etc.), a comprehensive review and evaluation of health risks of talc conducted by the Canadian government, and a number of other reviews, editorials and correspondence. In carefully reviewing and evaluating these materials, my opinions on genital talc use as a cause of ovarian cancer were supported and strengthened. To a reasonable degree of scientific certainty, it remains my opinion that genital talc use can cause ovarian cancer. I reserve the right to modify or refine my opinions based on additional scientific evidence that may emerge on this topic. I also reserve the right to review the reports and testimony of the defense experts.

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EXHIBIT A
Curriculum Vitae

Duke University Medical Center
Curriculum Vitae

Date Prepared: November 2023

Patricia Gripka Moorman, M.S.P.H., Ph.D.

Primary academic department: Department of Family Medicine and Community Health
(formerly Community and Family Medicine)
Duke University Medical Center

Present academic rank and title: Professor Emerita

Date and rank of first Duke faculty appointment: July 1, 2000, Assistant Professor

Medical licensure: N/A

Date of birth: December 19, 1957

Place of birth: Kansas City, Kansas, USA

Citizen of: United States of America

EDUCATION

	Institution	Year	Degree
High School	Bishop Ward High School Kansas City, KS	1975	Diploma
College	University of Kansas Lawrence, KS	1980	B.S. with distinction, Pharmacy
Graduate School	University of North Carolina – Chapel Hill Chapel Hill, NC	1989	M.S.P.H., Epidemiology
	University of North Carolina – Chapel Hill Chapel Hill, NC	1993	Ph.D., Epidemiology

PROFESSIONAL TRAINING AND ACADEMIC CAREER

Institution	Position/Title	Dates
Shalinsky Drugs, Kansas City, KS	Pharmacist	1980-1981
Community Pharmacy, Wrentham, MA	Pharmacist, Manager	1981-1982
Revco Drugs, Durham/Raleigh, NC	Pharmacist, Manager	1983-1993
Department of Epidemiology University of North Carolina - Chapel Hill	Graduate Research Assistant Teaching Assistant	1987-1993
Burroughs Wellcome Research Triangle Park, NC	Epidemiology Research Associate Summer Intern	1988
Department of Epidemiology Lineberger Comprehensive Cancer Center University of North Carolina - Chapel Hill	Research Assistant Professor	1994-1996
Dept. of Epidemiology and Public Health Yale Comprehensive Cancer Center Yale University School of Medicine New Haven, CT	Associate Research Scientist	1997-2000
Department of Epidemiology University of North Carolina - Chapel Hill	Adjunct Assistant Professor Adjunct Associate Professor	2000-2005 2005-present
Dept. of Community and Family Medicine Duke University Medical Center	Assistant Professor Associate Professor (non-tenured) Associate Professor (tenured) Clinical Research Unit Director (formerly Site-Based Research Director) Professor (tenured) Professor Emeritus	2000-2004 2004-2008 2008-2014 2009-2019 2014-2021 2021-present

PUBLICATIONS

Refereed Publications

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Letters

1. **Moorman PG.** Letter re: Breast cancer risk factors. *Drug Topics*. 2002; 146: 16.
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Book Chapters and Invited Papers

1. **Moorman PG**, Hames CG, Tyroler HA. Socioeconomic status and morbidity and mortality in hypertensive blacks. In Brest AN and Saunders E (eds): *Cardiovascular Clinics: Cardiovascular Diseases in Blacks*. FA Davis Company, Philadelphia, 1991, 179-93.
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3. Hulka BS, **Moorman PG**. Breast cancer: Hormones and other risk factors, *Maturitas*. 2001; 38: 103-13.
4. **Moorman PG**, Terry PD. Dairy products and breast cancer. 2003. United Kingdom Dairy Council. (Invited paper)
5. **Moorman PG**, Berchuck A. Comment on: Hormone replacement therapy does not increase risk for ovarian cancer in women with BRCA mutations. *North American Menopause Society First to Know*. Feb. 15, 2006. www.menopause.org/news.html.
6. **Moorman PG**, Hamilton RJ. Statins and cancer risk: what do we know and where do we go from here? *Epidemiology*. 2007; 18: 194-6. (Invited paper)

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8. **Moorman PG**. Ovarian failure after pre-menopausal hysterectomy. *European Obstetrics & Gynecology*. 2012; 7: 35-8. (Invited paper)
9. **Moorman PG**. Genetic markers for ovarian cancer risk: are we close to seeing a clinical impact? *Personalized Medicine*. 2012; 9: 565-7. (Invited paper)
10. **Moorman PG**. Should women at high risk for cancer use oral contraceptive pills? *Personalized Medicine*. 2015, 12: 533-5. (Invited paper)

Technical Reports

1. **Moorman PG**, Goldstein K, Coeytaux R, Myers ER, Strauss J, Van Houtven C, Shepherd-Banigan M, Brancu M, Von Isenberg M, Van Noord M, Conklin J, Lallinger K, Schmidt R, McBroom Brooks A, Sanders-Schmidler G. Topic Brief: Nutritional needs of older women. Prepared for Office of Women's Health and Agency for Healthcare Research Quality (AHRQ), 2017.
2. Myers ER, Strauss J, Van Houtven C, Goldstein K, Shepherd-Banigan M, Brancu M, **Moorman PG**, Coeytaux R, Von Isenberg M, Van Noord M, Conklin J, Lallinger K, Schmidt R, McBroom Brooks A, Sanders-Schmidler G. Topic Brief: Maternal Health. Prepared for Office of Women's Health and Agency for Healthcare Research Quality (AHRQ), 2017.
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Non-authored Publications (acknowledged for contributions)

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Presentations and Published Abstracts (selected)

Moorman PG, Newman B, Butler LM, Ostermeyer EA, Friedman LS, Millikan RC, Liu ET, King MC. Inherited susceptibility at BRCA1 in a population-based sample. Society for Epidemiologic Research, Boston, MA, June 1996

Rockhill B, Newman B, **Moorman P**, Millikan R, Weinberg C. Summary attributable fraction and breast cancer risk factors. Society for Epidemiologic Research, Boston, MA, June 1996.

Furberg H, Newman B, **Moorman P**, Millikan R. Lactation and breast cancer risk. Society for Epidemiologic Research, Edmonton, Alberta, Canada, June 1997.

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Moorman PG. Menopausal hormones and risk of breast cancer. Carolina Breast Cancer Study Participant Symposium, Chapel Hill, NC, April 2000

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Hall IJ, Newman B, Millikan RC, **Moorman PG**. Comparative analysis of breast cancer risk factors among African-American women and white women. Congress of Epidemiology, Toronto, Ontario, Canada, June 2001.

Moorman PG, et al. Nuts and bolts of field studies: things they didn't teach you in school. Congress of Epidemiology, Toronto, Ontario, Canada, June 2001. (Invited talk)

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Moorman PG. Population-based study of breast cancer among African-American and White women in North Carolina. North Carolina Central University, Durham, NC, January 2003. (Invited talk)

Moorman PG. Medication use and breast cancer risk. Psychiatry and Behavioral Sciences Grand Rounds, Memorial Sloan-Kettering Cancer Center, New York, NY, March 2003. (Invited talk)

Sansbury L, Millikan R, Schroeder J, **Moorman P**, North K, Sandler R. Use of non-steroidal anti-inflammatory drugs, cyclooxygenase-2 Val411Ala polymorphism and association with colon cancer in a population-based study of African Americans and whites. 3rd Annual AACR International Conference, Seattle, WA, October 2004.

Schildkraut JM, Berchuck A, Murphy S, Marks J, **Moorman P**, Calingaert B, Halabi S. Trinucleotide repeat polymorphisms in the androgen receptor gene and risk of ovarian cancer. 3rd Annual AACR International Conference, Seattle, WA, October 2004.

Moorman PG, Sesay J, Nwosu V, Millikan R. Non-steroidal anti-inflammatory drugs, COX2 polymorphism and breast cancer: a study of gene-environment interactions. Triangle Cancer and Disparities Symposium, North Carolina Central University, Durham, NC, March 2005.

Moorman PG. Racial disparities in breast cancer: problem or opportunity? Johnson C. Smith University, Charlotte, NC, September 2005. (Invited talk)

Trivers K, Gammon M, Abrahamson P, Lund MJ, Kaufman J, **Moorman P**, Cai JW, Porter P, Brinton L, Eley JW. Reproductive factors and breast cancer survival in women less than 55 years of age. 4th Annual Conference on Frontiers in Cancer Prevention Research, Baltimore, MD, November 2005.

Moorman PG. The role of epidemiology in the drug development process. University of Ferrara, Ferrara, Italy, May 2006. (Invited talk)

Moorman PG. Racial disparities in breast cancer: risk factors through survival. Women's Health Research Symposium - Untying the Pink Ribbon: Advances in Breast Cancer. University of Maryland School of Medicine. Baltimore, MD, March 2008. (Invited talk)

Moorman PG, JM Schildkraut JM, ES Iversen ES, ER Myers ER, M Gradison M1, N Warren-White N, F Wang. Weight gain after pre-menopausal hysterectomy. Society for Epidemiologic Research, Chicago, IL, June 2008.

Moorman PG. Non-steroidal anti-inflammatory drugs (NSAIDs) as chemopreventives for cancer: are they ready for prime time? Genetics and Environmental Mutagenesis Society 26th Annual Fall Meeting. Research Triangle Park, NC, October 2008. (Invited talk)

Moorman PG. Introduction to cancer epidemiology. Osher Lifelong Learning Institute lecture series. Chapel Hill, NC, September 2009. (Invited talk)

Moorman PG. Challenges of epidemiologic research in the genomic era: the example of ovarian cancer. Environmental Mutagen Society Annual Meeting, St. Louis, MO, October 2009 (Invited talk)

Moorman PG. Epidemiology in clinical research: beyond randomized controlled trials. Duke University Health System Clinical Education and Professional Development Series, Durham, NC, January 2010. (Invited talk)

Moorman PG. Epidemiology in clinical research: beyond randomized controlled trials. Association of Clinical Research Professionals, Durham, NC, June 2010. (Invited talk)

Moorman PG. The role of epidemiology in understanding disparities in breast cancer. Duke Oncology Symposium – Advances in Surgical and Treatment Options for Breast and Colorectal Cancer. Raleigh, NC, May 2011. (Invited talk)

Østbye T, **Moorman P.** Measurement dilemmas: validity, reliability and messy data. Family Medicine Research Seminar Series, Duke University Medical Center, December 2011.

Moorman P, Østbye T. Research that can tell you something: internal and external validity in study design. Family Medicine Research Seminar Series, Duke University Medical Center, November 2011.

Myers ER, Havrilesky LJ, Gierisch J, **Moorman PG**, Dinan MA, Coeytaux R, Urrutia RP, Lowery WJ, Hasselblad V, McBroom AJ, Sanders GD. Using net benefits and acceptability curves to quantify uncertainty about tradeoffs between harms and benefits of oral contraceptives. Society for Medical Decision Making, Phoenix, AZ, October 2012.

Myers ER, Havrilesky LJ, Gierisch J, **Moorman PG**, Dinan MA, Coeytaux R, Urrutia RP, Lowery WJ, Hasselblad V, McBroom AJ, Sanders GD. Net effects of current patterns of oral contraceptive use on potentially fatal outcomes in the United States. Society for Medical Decision Making, Phoenix, AZ, October 2012.

Stouder A, Melcher B, Morgan PA, **Moorman PG**, Lin L, Stem J. Satisfaction Guaranteed? An Analysis of Lecturer Characteristics Associated with Physician Assistant Student Satisfaction. Physician Assistant Education Association Annual Education Forum, Seattle, WA, November 2012.

Moorman PG. The African American Cancer Epidemiology Study (AACES). Ovarian Cancer in Women of African Ancestry Emerging Consortium Meeting. Bethesda, MD, April 2013.

Moorman PG. Ovarian Cancer: What You Need to Know. Duke Cancer Institute, Cancer Awareness Workshop. Durham, NC, May, August and October 2014.

Moorman PG. Ovarian Cancer in African American Women: The Challenges of Studying a Less Common Cancer in a Minority Population. Duke Cancer Institute Cancer Control and Population Sciences Seminar Series. Durham, NC, July 2014.

CONSULTANT APPOINTMENTS

National Institutes of Health, Center for Scientific Review

- Epidemiology and Disease Control Subcommittee 2 (EDC-2): Oct. 2000, Feb. 2001
- Special Emphasis Panels: Nov. 2001, Mar. 2002, Nov. 2002, Nov. 2003, July 2004, Nov. 2004, June 2005, Mar. 2006, Nov. 2006, Mar. 2007, July 2007, Nov. 2008, June 2009, July 2009, July 2010, Oct. 2010, Sept. 2011, Dec. 2013, Mar. 2017, Nov. 2017
- Small Grants Program for Cancer Epidemiology: Nov. 2001, Mar. 2003, June 2016, Mar. 2017, June 2017, June 2018, Nov. 2018, Apr. 2019
- National Cancer Institute, Program Project Review: Jan. 2003, Aug. 2003, Dec. 2003.
- SPORE (Specialized Program of Research Excellence) Review: Breast Cancer Feb. 2005, Ovarian Cancer June 2008, Feb. 2009.

Centers for Disease Control and Prevention. Defining the Public Health Research Agenda for Ovarian Cancer. Invited panel participant. Nov. 2008.

Susan G. Komen for the Cure, Study Section Chair for Post-Doctoral Fellowship in Risk and Prevention, 2010.

Susan G. Komen Breast Cancer Foundation, Study Section Chair for Risk, Prevention and Epidemiology, Member of Programmatic Review Committee, 2005 – 2007.

Susan G. Komen for the Cure/Susan G. Komen Breast Cancer Foundation, Scientific Reviewer, 2003 - 2011.

Department of Defense Breast Cancer Research Program Scientific Peer Review, 1998, 2005, 2007, 2008, 2009, 2013.

Department of Defense Breast Cancer Research Program, Study Section Chair for Training - Epidemiology and Prevention, 2013.

Department of Defense Ovarian Cancer Research Program Scientific Peer Review, 2015, 2016.

Department of Defense Ovarian Cancer Research Program, Study Section Chair for Investigator Initiated Research II, 2018.

National Cancer Institute, Center for Global Health, Data Monitoring Committee for United States – Latin American Cancer Research Network, 2013

CODA, Inc., Research Triangle Park, NC. IRB member, 2004.

National Institute of Environmental Health Sciences Special Emphasis Panel, Technical Evaluation of Support Services for Epidemiology, NIEHS Epidemiology Branch. May 1998.

PROFESSIONAL AWARDS AND SPECIAL RECOGNITIONS

Honorary Physician Assistant, Duke University Medical Center Physician Assistant Program - 2018

Certificate of Appreciation, Duke University Medical Center Physician Assistant Program – 2008

Delta Omega, Public Health Honorary – 1994

The Endocrinologist, Editorial Prize for Volume II – 1993

Research Service Award, National Cancer Institute - 1988-91

Edward E. Smissman Award for Medicinal Chemistry, University of Kansas – 1980

Walter F. Enz Award for Pharmaceutical Chemistry, University of Kansas – 1980

Watkins-Berger Scholarship, University of Kansas - 1975-1980

State of Kansas Scholarship, University of Kansas - 1976-1980

ORGANIZATIONS AND PARTICIPATION

University of North Carolina School of Public Health Alumni Association, Epidemiology Section President, 2001-2002.

Society for Epidemiologic Research

American Pharmaceutical Association

TEACHING RESPONSIBILITIES

Courses Taught

Evidence Based Medicine-I, Duke University, Department of Community and Family Medicine, Physician Assistant program. Primary instructor, 2004-2017.

Evidence Based Medicine-II, Duke University, Department of Community and Family Medicine, Physician Assistant program. Co-Instructor, 2003-2018.

Evidence Based Medicine-I, Duke University, Department of Community and Family Medicine, Physician Assistant program. Lecturer and seminar instructor, 2003.

Epidemiology and Research Methods (PAP 255), Duke University, Department of Community and Family Medicine, Physician Assistant program. Seminar instructor, 2001-2002.

Epidemiology of Cancer (CDE 532B), Yale University, Department of Epidemiology and Public Health. Course director, 1997-2000.

Co-developer of departmental Master's Comprehensive Examination, University of North Carolina-Chapel Hill, Department of Epidemiology, 1995-1996.

Cancer Epidemiology (EPID 233), University of North Carolina-Chapel Hill, Department of Epidemiology, Teaching Assistant, 1992-1993.

Principles of Epidemiology (EPID 160), University of North Carolina-Chapel Hill, Department of Epidemiology, Teaching Assistant, 1990.

Student Mentoring

Helena Furberg, MSPH, University of North Carolina, 1996, Committee Member

Pamela M. Marcus, PhD, University of North Carolina, 1997, Committee Member

Stella Chang, MPH, Yale University, 1997, Committee Member

Mary Riciutti, MPH, Yale University, 1999, Committee Chair

Edward A. Lew, MPH, Yale University, 1999, Committee Member

Shelley Goodstine, MPH, Yale University, 1999, Committee Member

Rupal Desai, MPH, Yale University, 1999, Committee Member

Pei-Yu Lin, MPH, Yale University, 2000, Committee Chair

Lisa Calvocoressi, Ph.D., Yale University, 2003, Dissertation Reader

Rebecca Cleveland, Ph.D., University of North Carolina, 2003, Committee Member

Leah Sansbury, Ph.D., University of North Carolina, 2004, Committee Member

Sumitra Shantakumar White, Ph.D., University of North Carolina, 2006, Committee Member

Katrina Trivers, Ph.D., University of North Carolina, 2006, Committee Member

Amy Dailey, Ph.D., Yale University, 2006, Dissertation Reader

Enid Rivera, M.D., Duke University, 2008, 3rd year Medical Student Preceptor

Alexis Gaines, Duke University, 2013, Master's Committee Member

Chioma Erondu, Duke University, 2013-14, 3rd year Medical Student Preceptor

Tolulope Teniola, Duke University 2016-17, 3rd year Medical Student Preceptor

Tengteng Wang, Ph.D., University of North Carolina, 2019, Committee Member

COMMITTEES AND SERVICE

Duke University School of Medicine Institutional Review Board (IRB), 2005-2021

Research Mentoring Awards Selection Committee, Duke University School of Medicine, 2018-2021

Standing Committee on Misconduct in Research, Duke University School of Medicine, 2017-2021

Duke CTSA Grant Reviewer: TL1 Awards 2020; KL2 Awards 2016, 2018, 2019, 2020, 2021; CTSI Pre-doctoral Awards 2019.

Duke REACH Equity Grant Reviewer, 2018.

Faculty Search Committee, Department of Family Medicine and Community Health, Duke University School of Medicine, 2018-19

Senior Faculty Advisory Committee, Office for Research Mentoring, Duke University School of Medicine, 2016

Academy of Mentors, Office of Faculty Mentoring, Duke University School of Medicine, 2014-16

Society for Epidemiologic Research. Reviewer for Tyrolier and Lilienfeld Prize Papers, 2015

Appointments, Promotions and Tenure Committee, Department of Community and Family Medicine, Duke University Medical Center. Committee Member, 2008-2018

Quality Assurance Sub-Committee for Clinical Research Units, Duke University Medical Center, Committee Chair, 2013-2014

Quality Assurance Sub-Committee for Clinical Research Units (formerly Site-based Research Units), Duke University Medical Center, Committee Member, 2011-2013

Path to Independence Faculty Mentoring Program, Duke University School of Medicine, Peer Reviewer , 2012-2018.

Society for Epidemiologic Research. Abstract reviewer for annual meeting, 2011

Cancer Prevention, Detection and Control Research Program, Duke University Medical Center, Cancer Control Pilot Study application reviewer, 2010, 2011

Executive Council, Department of Community and Family Medicine, Duke University Medical Center 2009-2017

Education Committee, Department of Community and Family Medicine, Duke University Medical Center, 2009-2017

Faculty Search Committee, Cancer Prevention, Detection and Control Research Program, 2010

Duke Cancer Institute, Editorial Advisory Committee Member, 2010-2011

Duke Comprehensive Cancer Center Annual Meeting, Judge for poster presentations, 2009

Director Search Committee, Cancer Prevention, Detection and Control Research Program, 2009

Partners Allied in Research (PAIR) Pilot Grant application reviewer, Cancer Prevention, Detection and Control Research Program, 2005

Editorial Reviewer

American Journal of Epidemiology	Annals of Epidemiology
Archives of Gynecology and Obstetrics	BMC Cancer
BMC Women's Health Review	Breast Cancer Research and Treatment
Breast Diseases	British Medical Journal-Cancer
British Journal of Clinical Pharmacology	Cancer
Cancer Biomarkers	Cancer Epidemiology Biomarkers and Prevention
Cancer Causes and Control	Clinical Breast Cancer
Cancer Research	Ethnicity and Disease
Epidemiology	International Journal of Cancer
Gynecologic Oncology	JAMA
International Journal of Epidemiology	Journal of the National Cancer Institute
Journal of Community Development	Journal of Women's Health
J of the Women's American Medical Assn	Lancet Oncology
Lancet	Pharmacogenomics
Nutrition and Cancer	Public Health Nutrition
PLOS One	Women and Health
Trends in Molecular Medicine	
Women's Health Issues	

CURRENT RESEARCH

- Epidemiology of breast and ovarian cancer
- Ovarian function after hysterectomy
- Racial differences in disease risk and outcomes
- Medication use and cancer risk
- Etiologic factors for uterine fibroids

EXTERNAL SUPPORT - PAST

Principal Investigator	% effort	Title of Project and Funding Source	Total Costs	Duration
Barbara Hulka	25%	High-Density Lipoprotein Cholesterol and Breast Cancer, National Cancer Institute, R03, Supported dissertation research	\$72,234	1992 – 1993
Beth Newman	100%	Carolina Breast Cancer Study, Project 2 SPORE in Breast Cancer, National Cancer Institute, P50.	\$1,275,000	1992 – 1995
Beth Newman	50%	Carolina Breast Cancer Study, Project 2 SPORE in Breast Cancer, National Cancer Institute, P50.	\$2,511,146	1995 - 1996

Patricia Moorman	50%	Medication Use and Breast Cancer in a Bi-racial Population, National Cancer Institute, R29-FIRST Award.	\$498,302	1996 – 2002
Patricia Moorman	0%	Carolina Breast Cancer Study Participant Symposium, North Carolina Division of American Cancer Society Small Grant.	\$2500	1997
Patricia Moorman	0%	Carolina Breast Cancer Study Participant Symposium, Susan G. Komen Breast Cancer Foundation Small Grant.	\$5000	1997
Joellen Schildkraut	10%	Carolina Georgia Center, Cancer Genetics Network, National Cancer Institute, U-24.	\$4,028,129	2002 – 2004
Patricia Moorman	0%	Non-steroidal Anti-Inflammatory Drugs and Breast Cancer: A Study of Gene-Environment Interactions among African-American and White Women, Minority Serving Institution Partnership Grant, Pilot Funds.	\$28,040	2003 – 2004
Celette Skinner	5%	Partnerships to Eliminate Disparities in Cancer Outcomes and Research, National Cancer Institute, National Cancer Institute.	\$517,743	2002 – 2006
Patricia Moorman	0%	Diversity Supplement to RO1 AG020162 Ovarian Failure Among Hysterectomized Women, National Institute on Aging (Note: Grant was awarded but post-doc accepted another position.)	\$169,720	2006
Andrew Berchuck	5%	Biological Basis for Chemoprevention of Ovarian Cancer, Department of Defense.	\$824,000	2002 – 2007
Stephen Freedland	5%	Weight Loss and Gain and Cancer Free Survival after Radical Prostatectomy in a Multiethnic Cohort. Prostate Cancer Foundation.	\$100,000	2007-2009
Joellen Schildkraut	10%	Genetic Modifiers of BRCA1 and BRCA2, Project 3 SPORE in Breast Cancer. National Cancer Institute.	\$1,795,862	2003 – 2009
Joellen Schildkraut	10%	Molecular Epidemiology of Ovarian Cancer. National Cancer Institute.	\$3,750,000	2003 – 2010
Patricia Moorman	40%	Ovarian Failure among Hysterectomized Women. National Institute on Aging.	\$3,781,480	2003 - 2010
Patricia Moorman (Sub-contract PI)	3%	Cancer Genetics Network. National Cancer Institute.	~\$25,000	2010 – 2012

Laura Havrilesky	15%	Oral Contraceptive Use for the Primary Prevention of Ovarian Cancer. Agency for Healthcare Research and Quality	\$486,476	2010 - 2012
Jeffrey Marks	5%	Atlantic Breast and Gynecologic Clinical Validation Center. National Cancer Institute	>\$1,500,000	2010 - 2013
Cathrine Hoyo	5%	Disparities in Cervical Cancer Precursors and Deregulation of Imprinted Genes National Cancer Institute	~\$200,000	2012 – 2013
Emanuel Trabuco (Moorman, Duke PI)	2%	Anti-Müllerian Hormone as a Marker of Ovarian Reserve in Women with and without Hysterectomy. Mayo Clinic Internal Funds	\$100,000	2012 – 2013
Evan Myers	10%	Systematic Review of Cancer Screening Literature for Updating American Cancer Society Breast Cancer Screening Guidelines American Cancer Society	~\$400,000	2013 - 2014
Joellen Schildkraut	9%	Cancer Education and Career Development Training Grant. National Cancer Institute	~\$1,400,000	2009 – 2014
Patricia Moorman (Sub-contract PI)	5%	Rare Cancer Genetics Network National Cancer Institute	~\$240,000	2010 – 2016
Joellen Schildkraut (Moorman, co-PI)	20%	Epidemiology of Ovarian Cancer in African American Women National Cancer Institute	~\$12,000,000	2010 – 2017
Gillian Sanders	10%	Management of Infertility Evidence-Based Practice Center		2015-2016
Gillian Sanders	10%	Management of Labor Dystocia Evidence-Based Practice Center		2016
Gillian Sanders	15%	Office of Women's Health – Topic Development Evidence-Based Practice Center		2016
Evan Myers	5%	Comparing Management Options for Management: Patient-centered Results for Uterine Fibroids (COMPARE-UF) PCORI	~\$19,000,000	2014 – 2018
Joellen Schildkraut (Moorman,sub-contract PI)	13%	Exploring Factors Related to Racial Disparities in Ovarian Cancer Incidence and Survival: The OCWAA (Ovarian Cancer in Women of African Ancestry) Consortium National Cancer Institute	~\$450,000	2017 - 2021

Joellen Schildkraut 5% Ovarian Cancer Survival in African American Women, National Cancer Institute 2020-2021

EXHIBIT B
2021 Report Addendum

**ADDENDUM TO
RULE 26 EXPERT REPORT OF
PATRICIA G. MOORMAN, MSPH, PHD
DATED NOVEMBER 16, 2018**

Date: April 21, 2021



Patricia G. Moorman

Patricia G. Moorman, MSPH, PHD

Since my report of November 16, 2018, additional material related to the topic of my report has become available. The attached list of references identifies materials I found most relevant to this subject. The new material consists of FDA results of testing talc-containing cosmetic products for asbestos, new epidemiologic data specific to ovarian cancer, mechanistic data, data on talc analysis in ovarian tissue, a systemic review and meta-analysis, a narrative review, and opinion pieces and letters to the editor.

In my 2018 report, I described my methodology to review, assess, and weigh material relevant to the inquiry of whether there is an association between talcum powder product use and ovarian cancer. I used the same critical method of review with this new material, for individual publications and relative to the cumulative body of evidence on this subject. Generally, this new material provides additional evidence that supports the causal connection between talcum powder product use and ovarian cancer.

After incorporating this new material within the body of evidence and analysis of my 2018 report, my opinion is supported and strengthened. Based on the evidence in total, it is my opinion with a reasonable degree of scientific certainty that use of talcum powder products can cause ovarian cancer. I reserve the right to modify or refine my opinions based on additional scientific evidence that may emerge on this topic.

To assist in understanding the new evidence on this topic, I discuss four papers published since my 2018 report, which provide the most relevant additional epidemiologic data and perspective on ovarian cancer and talc use: Gabriel, 2019; O'Brien, 2020; Taher, 2019; and Goodman, 2020.

Two of these papers described new analyses of the association between talc or body powder use and ovarian cancer (Gabriel, 2019; O'Brien, 2020). Notably, prior publications from these study populations had reported on talc and ovarian cancer, (Cramer, 2016; Gonzalez, 2016; Gertig, 2000; Houghton, 2014) which is important to bear in mind when considering the new information that is to be gleaned from these papers. The other papers are a systematic review and meta-analysis (Taher, 2019) and a narrative review (Goodman, 2020).

Gabriel, 2019

The first paper by Gabriel and colleagues (2019), described the effects of talc use and douching, individually and jointly, on ovarian cancer risk and other genital tract conditions in a case-control study conducted in Massachusetts and New Hampshire. Consistent with a previous report on this study population, (Cramer, 2016) there was a statistically significantly increased risk of ovarian cancer among women who reported use of talc (odds ratio (OR) 1.30, 95% confidence interval (CI) 1.13-1.50), with a significant trend of increasing risk with greater use of talc ($p=0.0001$). Similar associations with talc use were reported among women who reporting douching (OR 1.32, 95% CI 0.95-1.82) and those who did not douche (1.28, 95% CI 1.09-1.51). In contrast to the talc findings, douching was not significantly associated with ovarian cancer (OR 0.98, 95% CI 0.83-1.17, overall; OR 1.03, 95% CI 0.77-1.38 among talc users; and OR 0.94, 95% CI 0.76-1.16 among those who never used talc).

This paper sheds light on two points that have been raised in regard to whether the association between talc use and ovarian cancer is “real”, namely recall bias and uncontrolled confounding. Recall bias is often invoked as an explanation for the observed association between talc use and ovarian cancer in case-control studies, with the idea that women with ovarian cancer are more likely to recall their exposure to talc than control women, leading to a spurious increase in risk. If this indeed were the case, one would expect that the ovarian cancer cases similarly would be more likely to recall use of douching products. Both are non-prescription products used for feminine hygiene, so if there was over-reporting by cases, it would be reasonable to see it to a similar degree for both types of products. The fact that the investigators found no association between ovarian cancer and douching, but a significant association between ovarian cancer and talc, argues against the association with talc being a result of recall bias.

In regard to uncontrolled confounding, most of the papers describing the association between talc use and ovarian cancer have not examined douching as a potential confounding variable. After the publication of the Gonzalez paper in 2016, (Gonzalez, 2016) which reported a significant association between douching and ovarian cancer, some argued that the association between talc use and ovarian cancer could have been due to the uncontrolled confounding effects of douching. The Gabriel paper accounted for the potential confounding effect of

douching by presenting results for both women who reported douching and those who never douched, with significant associations between talc use and ovarian cancer in both groups. These data, along with data from prior studies that either controlled for the possible confounding effects of douching in their analyses (Harlow, 1992; Gonzalez, 2016) or reported no association between douching and ovarian cancer (Hartge, 1983), argue against the notion that the association between talc use and ovarian cancer is due to uncontrolled confounding.

O'Brien, 2020

The second paper reporting a new analysis of talc and ovarian cancer (O'Brien, et al., 2020) combined data from four cohorts: the Nurses Health Study I and II, the Sister Study and the Women's Health Initiative. All of these cohorts have previously reported on the association between talc use and ovarian cancer (Gertig, 2000; Gonzalez, 2016; Houghton, 2014) except for the Nurses Health Study II, which contributed 76 cases of the 2213 ovarian cancer cases in this analysis.

Overall results were quite consistent with their previous reports and with pooled analyses from meta-analyses, reporting a pooled hazard ratio (HR) of 1.08 (95% CI 0.99-1.17), and a statistically significantly increased risk among women with a patent reproductive tract (HR 1.13, 95% CI 1.01-1.26). The investigators reported many sub-group analyses including personal characteristics such as age, BMI and menopausal status and tumor characteristics such as invasiveness and histotype (e.g., Table 4, Figure, Supplemental Tables 3 and 4). While the majority of reported HRs were not statistically significant, it is noteworthy that the vast majority of them were greater than 1. If in fact there was no association between talc use and ovarian cancer, one would expect that the HRs would cluster around the null value of 1, with roughly equal numbers of HRs above and below 1. The fact that most HRs were above 1 is contrary to what one would expect if talc truly were not associated with risk for ovarian cancer.

As is common in epidemiologic papers, the authors described some of the strengths and limitations of their study. As was discussed in my previous report, the cohort studies typically note that they are not subject to recall bias because information on talc use was obtained before the diagnosis of ovarian cancer. However, O'Brien et al, did not discuss the probable non-differential misclassification of talc use due to errors in recall or the phrasing used in the

questions to assess talc exposure. In these cohort studies, women were asked to recall their use of a product that may have been used decades ago. As noted in Table 1 of the O'Brien paper, the age at assessment of powder use ranges from 35 to 81 years. Given that the majority of women initiate talc use in their teens or 20s, it is apparent that some women were being queried about a product that they used as much as 50 years earlier, and some women likely misreported their exposure. The misreporting of the exposure in the Sisters Study was likely greater than the other studies due to their exposure assessment questions. In their previous report, exposure was based on use in the prior 12 months (Gonzalez, 2016). In the analysis in the O'Brien paper, exposure was based on use of talc in the prior 12 months or at ages 10 to 13 years, which is a slight improvement over what was reported in Gonzalez, 2016, but still would have resulted in misclassification of talc exposure in a substantial proportion of women. The result of such non-differential misclassification is generally a bias towards the null, resulting in an attenuation of the HR.

An additional concern with the cohort studies is that because of the age of the cohorts at the time of talc exposure assessment, a substantial number of the women in the cohorts who had ovarian cancer were excluded. Using information from the footnote to Table 1, the table below shows the number of women in the cohorts who were excluded because they had a diagnosis of ovarian cancer prior to baseline (i.e., time of questionnaire about powder use) and the number of included cases that were diagnosed after baseline. While it is appropriate from an analytic standpoint to include only cases diagnosed after baseline (incident cases), it is apparent that this could limit the generalizability of these findings, because the women included in the cohorts are older. If talc use is more strongly associated with ovarian cancer diagnosed at younger ages, the use of cohorts of older women would be less able to detect such an association.

	Nurses Health Study I	Nurses Health Study II	Sister Study	Women's Health Initiative
Excluded	174	287	225	641
Included	1258	76	220	659

Taher, 2019

Taher, et al. (Taher, 2019; Kadry Taher, 2020) published a systematic review and meta-analysis on perineal use of talc powder and ovarian cancer that was funded by Health Canada.

The results of their meta-analysis were concordant with two other recent meta-analyses (Berge, 2017; Penninkilampi, 2018), reporting an overall relative risk for ovarian cancer associated with talc use of 1.28 (95% CI 1.20-1.37). They also noted a possible increasing trend in ovarian cancer risk with increasing cumulative exposure to talc, albeit with a high degree of uncertainty. In addition to the epidemiologic data, the authors also evaluated data from non-human studies to evaluate the carcinogenicity of talc. In their evaluation of potential biological mechanisms, they made the statement the “Talcum powder has been asbestos-free since the (sic) 1976 where the specifications for cosmetic talc were developed”, which based on recent evaluations of talcum powder products has been shown to be untrue. (FDA, 2020) Nonetheless, after consideration of data from both human and non-human studies, their overall conclusion was consistent with the IARC evaluation that perineal exposure to talc is a possible cause of ovarian cancer in humans.

Goodman, 2020

Goodman, et al. (Goodman, 2020) published a review of talc and ovarian cancer that was funded by the Cosmetics Alliance Canada and concluded that the evidence does not support a causal association between perineal talc use and ovarian cancer. This paper did not present new data, but rather the authors’ evaluation and interpretation of previously-published data.

In regard to the epidemiologic data, several of the points made in this article deserve comment. The authors discuss the possibility of recall bias in case-control studies at length and make the point that an “approach to reducing recall bias is to design surveys such that subjects are asked about a variety of chemical exposures in addition to the exposure of interest (i.e., talc in this case) such that subjects are unaware of the main hypothesis of the study and do not become fixated on one environmental exposure in particular. In some studies, questionnaires employed are focused on talc use, and no other environmental exposures (besides smoking) are assessed. These questionnaires are not designed to mitigate recall bias.” This characterization of questionnaires used in the case-control studies is not accurate. All of the larger case-control studies that reported on talc and ovarian cancer have published on numerous other exposures in their study populations including reproductive characteristics, medication use, smoking, alcohol use, family history, socioeconomic status, etc. Surveys used in case-control studies typically collect detailed information on a wide variety of known and suspected ovarian cancer

risk factors. As such, it is highly unlikely that the subjects were “fixated” on talc exposure in particular, leading to substantial recall bias.

In their discussion of recall bias, the authors also fail to mention that if recall bias were the likely explanation for the increased risk seen with talc exposure, one would also expect to see increased risk for similar exposures. This has not been the case, as was discussed in detail above for douching, a feminine hygiene practice that one would expect would be recalled similarly to talc use.

These authors also invoke uncontrolled confounding as a possible explanation for the association between talc use and ovarian cancer in case-control studies. Although it is theoretically possible that there is some factor(s) associated with both talc use and ovarian cancer that acts as a confounder of the association, no such confounder has been identified. While this is a concern that has been raised by others skeptical of the association, an increased risk of ovarian cancer with talc use has been reported repeatedly since 1982 and during this nearly four-decade period, no one has reported a confounding factor that could explain away the association.

Another point worth addressing in the Goodman paper is that their discussion of the biological plausibility of talc being a cause of ovarian cancer completely ignores the issue of asbestos in talcum powder products. The introduction states that “In 1976, cosmetic-grade talc specifications required that there be no detectable fibrous, asbestos minerals”. However, there is no acknowledgment in their paper that various analyses have found asbestos in talcum powder products manufactured after 1976, including one directed by the U.S. Food and Drug Administration (FDA, 2020) that resulted in the recall of Johnson & Johnson’s baby powder in October 2019. Asbestos has been established as a cause of ovarian cancer (IARC, 2012) and the Occupational Safety and Health Administration (OSHA) (<https://www.osha.gov/asbestos>) has stated that there is no safe level of asbestos exposure. The authors’ failure to discuss asbestos in talcum powder products as a biologically plausible mechanism severely undermines their conclusion that “there is insufficient evidence for any proposed mechanism by which talc might possibly cause ovarian cancer.”

REFERENCES

Casey R, Larkin TP. Ovarian cancer and "tainted talc": what treating physicians need to know. *Mo Med* 2019; Mar-Apr;116(2):83-86.

Chirino OR. Tainted talc and ovarian cancer. *Mo Med*. 2019 May-Jun;116(3):170-171.

Cramer DW, Vitonis AF, Terry KL, Welch WR, Titus LJ. The association between talc use and ovarian cancer; a retrospective case-control study in two US states. *Epidemiology* 2016; 27:334-46.

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EXHIBIT C
Testimony List

DEPOSITION OR TRIAL TESTIMONY PROVIDED IN LAST FOUR YEARS

Deposition Testimony

U.S. District Court, Southern District of Florida, *In re: Zantac (Ranitidine) Products Liability Litigation*, MDL No. 2924: May 16-17, 2022 and October 21, 2022

Trial Testimony

None